

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW MEXICO**

UNITED STATES OF AMERICA,

Plaintiff,

vs.

Case No.: 15-CR-2030 WJ

ROY HEILBRON,

Defendant.

**MEMORANDUM OPINION AND ORDER DENYING DEFENDANT'S *DAUBERT*
MOTION TO EXCLUDE THE EXPERT TESTIMONY OF NEAL SHADOFF, M.D.**

THIS MATTER comes before the Court upon Defendant Roy Heilbron's Motion for a Pretrial *Daubert* Hearing and to Exclude Evidence, filed on October 10, 2016 (**Doc. 30**). While the Court was initially contemplating having oral argument and testimony on Defendant's *Daubert* Motion, now that the motion is fully briefed and the Court has reviewed the relevant pleadings, the Court finds that a hearing on this Motion would be an ineffective use of time and resources for all concerned.¹ Therefore, the Court **DENIES** Defendant's *Daubert* Motion and will allow Neal Shadoff, M.D. to offer expert opinion testimony at trial.

BACKGROUND

Defendant Roy Heilbron, M.D., is charged with 21 counts of healthcare fraud in violation of 18 U.S.C. § 1347(a)(2) and three counts of wire fraud, in violation of 18 U.S.C. § 1343. During the timeframe pertinent to this case, Defendant practiced cardiology and internal medicine. He described his approach as "holistic." He operated a medical clinic in Santa Fe,

¹ Although the Court initially granted Defendant's request for a *Daubert* hearing (Doc. 32), for the reasons stated in this Memorandum Opinion and Order, the Court finds it is no longer necessary to hold a hearing on Defendant's Motion.

New Mexico.

The Indictment alleges, in pertinent part, that Defendant committed healthcare fraud by submitting fraudulent claims to Medicare and a number of private health care insurers. The United States alleges these claims were fraudulent because Defendant knew at the time they were submitted that they falsely stated diagnoses, sought payment for services Defendant knew to be medically unnecessary, and sought payment for services that were not performed. The Indictment further alleges Defendant submitted claims to the health care insurers for tests with false diagnoses codes to justify the tests. As part of this scheme, Defendant ordered and performed medically unnecessary tests; inserted false symptoms, observations, and diagnoses into patients' medical charts to provide written support for the tests he ordered or performed; frequently submitted claims for two consecutive dates of service when the patients only visited the office on one date; misused coding modifiers; caused claims to be submitted to health care benefit programs for procedures or treatments that were never performed; placed and caused to be placed in patients' medical charges clinical notes, diagnostic test results, and ultrasound images that were photocopies of other patients' records; used photocopied order sheets that contained pre-filled symptoms or diagnosis codes; and, when the private healthcare plans requested additional documentation in support of submitted claims, submitted notes, reports, images, and order sheets he knew to be false. *See* Doc. 2, at 4–7.

The United States identified Neal Shadoff, M.D. as its expert to testify that medical tests and procedures performed by Defendant were medically unnecessary. More specifically, Dr. Shadoff plans to testify about “current general cardiology literature regarding evaluation and management of patients; internal medicine and cardiovascular disease; diagnosis and treatment of patients for cardiovascular and other disease; the appropriateness of diagnoses and treatment

provided by the Defendant; the medical necessity of treatment provided and recommended by the Defendant.” Doc. 28, at 1.

Defendant filed a Motion for a Pretrial Daubert Hearing and to Exclude Evidence on October 10, 2016 (**Doc. 30**). The United States filed a Response on November 3, 2016 (**Doc. 34**). Defendant filed a Reply on November 28, 2016 (**Doc. 44**).

LAW ON DAUBERT

“Rule 702 imposes a gatekeeping function on district courts to ensure expert testimony is admitted only if it is relevant and reliable . . . Even if scientifically valid, the expert testimony must fit—it must relate to a disputed issue in the case.” *Etherton v. Owners Ins. Co.*, 829 F.3d 1209, 1217 (10th Cir. 2016) (internal quotations and citations omitted); *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 597 (1993). An otherwise qualified expert witness may testify if “the expert’s scientific, technical or other specialized knowledge will help the trier of fact to understand the evidence or determine a fact in issue.” Fed. R. Evid. 702 also addresses the reliability requirements for expert testimony found to be helpful to the trier of fact.

With regard to reliability, the Court’s gate-keeping function involves a two-step analysis. First, the Court must determine whether the expert is qualified by “knowledge, skill, experience, training or education” to render an opinion. *See* Fed. R. Evid. 702. The second step of the Court’s reliability analysis, taken once the witness is found to be qualified, is to determine whether the expert’s opinions themselves are “reliable” under the principles set forth under *Daubert* and *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137 (1999). *See Ralston v. Smith & Nephew Richards, Inc.*, 275 F.3d 965, 969 (10th Cir. 2001)

“The reliability determination calls for a ‘preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that

reasoning or methodology properly can be applied to the facts in issue.” *Etherton*, 829 F.3d at 1217 (quoting *Daubert*, 509 U.S. at 592–93). In *Daubert*, the Supreme Court “offered five non-exclusive considerations: whether the theory or technique has (1) been or can be tested, (2) been peer-reviewed, (3) a known or potential error rate, (4) standards controlling the technique’s operation, and (5) been generally accepted by the scientific community.” *See Daubert*, 509 U.S. at 593–94.

Once reliability is established, the court must determine whether the expert’s testimony is relevant. Evidence must only have “any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence.” Fed. R. Evid. 401; *See United States v. Leonard*, 439 F.3d 648, 651 (10th Cir. 2006). The standard of relevance is liberal. *See Daubert*, 509 U.S. at 587. Although the threshold inquiry is low, the rules do “not sanction the carte blanche admission of whatever evidence a defendant would like. The trial judge is the gatekeeper under the Rules of Evidence.” *United States v. Jordan*, 485 F.3d 1214, 1218 (10th Cir. 2007).

DISCUSSION

I. Qualifications

Defendant does not appear to legitimately challenge Dr. Shadoff’s qualifications to offer expert testimony in this case.² However, in performing its “gatekeeping” function, the Court considered Dr. Shadoff’s qualifications and finds he qualifies as an expert regarding the medical necessity of tests ordered by Defendant; the appropriateness of diagnoses and treatment provided by Defendant; evaluation and management of patients; internal medicine and cardiovascular disease; and diagnosis and treatment of patients for cardiovascular and other disease. *See*

² For example, in Defendant’s Reply, he argues Dr. Shadoff cannot qualify to testify as an expert because he is attempting to render medical opinions regarding treatment and procedures that are outside of his speciality and training. However, this argument bears more on the relevancy of Dr. Shadoff’s testimony. *See* § III.

Daubert, 509 U.S. at 589; *Lifewise Master Funding v. Telebank*, 374 F.3d 917, 928 (10th Cir. 2004) (An expert is required to possess “such skill, experience or knowledge in that particular field as to make it appear that his opinion would rest on substantial foundation....”). Dr. Shadoff earned his medical degree from Boston University. He is board certified by the American Board of Internal Medicine in Internal Medicine and Cardiovascular Disease. He has practiced cardiology for approximately thirty-three years. He has routinely ordered and interpreted many of the same cardiovascular and imaging studies that were ordered and reported by Defendant. Dr. Shadoff has experience and knowledge of current general cardiology literature regarding evaluation and management of patients similar to those seen by Defendant. The Court considered Dr. Shadoff’s curriculum vitae, and notes he has considerable experience. Dr. Shadoff has a substantial number of publications and has conducted ample research in the fields of cardiology and internal medicine. Although Defendant argues Dr. Shadoff is not qualified to testify because he has no knowledge, training, or practice in holistic medicine, a central issue in this case is the propriety of certain claims and diagnoses for cardiovascular problems that Defendant submitted to healthcare insurers under allegedly false pretenses. The United States points out that the healthcare insurers did not evaluate the appropriateness of diagnoses based on holistic medicine, because such insurers did not allow or pay claims for holistic services. Accordingly, the Court concludes Dr. Shadoff is qualified by knowledge, skill, experience, training and education to render expert opinions in this matter. *See Fed. R. Evid. 702.*

II. Reliability

Although Defendant’s principal challenge to Dr. Shadoff’s testimony is relevance, Defendant briefly discusses what he considers to be flaws in Dr. Shadoff’s methodology. Defendant argues Dr. Shadoff’s testimony is not reliable because Dr. Shadoff is board-certified

in internal medicine and cardiovascular disease, while Defendant is board-certified in holistic medicine. Defendant argues holistic medicine is a different specialty, with different training requirements and a clinical approach that is distinguishable from the traditional approach followed by Dr. Shadoff. Defendant claims Dr. Shadoff's opinion on the appropriateness of Defendant's testing procedures is not reliable, because Dr. Shadoff is not an expert in holistic medicine. Defendant makes a specific challenge to Dr. Shadoff's methodologies used in reaching his conclusion because Dr. Shadoff is applying the methodology of a cardiologist rather than a physician like Defendant who practices holistic medicine. Defendant maintains that while Dr. Shadoff's opinions may be generally accepted in the medical community of cardiology, his approach and techniques are rejected by those physicians practicing holistic medicine.

The United States points out that the main thrust of Defendant's challenge under *Daubert* is relevancy, and the Court agrees that Defendant appears to conflate reliability with relevancy in this case. For example, although Defendant states Dr. Shadoff's testimony is "not reliable," Defendant focuses on the fact that practitioners of holistic medicine employ different approaches than non-holistic practitioners. This argument focuses more on relevancy than it does on the reliability of Dr. Shadoff's methodology.

Nonetheless, the Court finds Dr. Shadoff's expert methodology in reaching his conclusions is sufficiently sound and concludes Dr. Shadoff's testimony is reliable. Employing his experience and knowledge as a practitioner of internal medicine and cardiology, Dr. Shadoff reviewed nine medical record charts from Defendant's office. Those records included medical record reports and billing records as well as an audio-recorded visit. In addition, Dr. Shadoff reviewed supplemental records of multiple other patients of Defendant. Dr. Shadoff concluded

many of the patient charts contained copies of the same reports and exams, and included no documentation that would reflect certain billing codes. *See Daubert*, 509 U.S. at 592 (district court must determine if the expert's proffered testimony has "a reliable basis in the knowledge and experience of his discipline"). His reasoning is sound because he is a cardiologist with extensive experience and Defendant diagnosed patients with certain cardiovascular problems and ordered tests routinely utilized in the field of cardiology. Dr. Shadoff does not need to be board-certified in holistic medicine to render opinions on the medical necessity of tests ordered by Defendant, a practitioner of cardiology and internal medicine. The gist of government's case is that Defendant knowingly submitted false claims to healthcare insurers. Those insurers did not credential physicians as practitioners of holistic medicine, nor did they allow or pay claims for holistic services. Thus, Dr. Shadoff's methodologies in reaching his expert conclusions are sufficiently reliable.

III. Relevance

Defendant's principal challenge is to the legal relevance of Dr. Shadoff's testimony, which is the last inquiry under *Daubert*. Defendant maintains that Dr. Shadoff's expert testimony is not relevant because Dr. Shadoff is rendering an opinion on the appropriateness of Defendant's testing procedures, but Dr. Shadoff is not an expert in holistic medicine. Thus, Dr. Shadoff's proffered testimony is not relevant to the diagnostic approach of holistic medicine.

In response, the United States contends that Dr. Shadoff's expected testimony is relevant because Defendant was credentialed by each of the healthcare insurers as a cardiologist and an internist, not as a practitioner of holistic medicine. None of the alleged victim health care insurers credentialed physicians as practitioners of holistic medicine. The United States further argues Defendant knew that the alleged victim health insurers evaluated the appropriateness of

the diagnoses he rendered and the medical necessity of the services he claimed to provide based on what was medically accepted for cardiovascular and internal medicine. The alleged victim health insurers did not evaluate the appropriateness of diagnoses on the basis of what was accepted for holistic medicine, nor did they evaluate the medical necessity for holistic services, because they did not allow or pay claims for such services. Moreover, Defendant did not submit claims for holistic services, but rather submitted claims for services related to internal medicine and cardiovascular disease.

The United States further argues Dr. Shadoff is qualified to testify as to whether the services for which Defendant submitted claims were medically necessary. Medicare and the three private insurers listed in the Indictment only paid claims for services and procedures that were medically necessary. In submitting a claim to these health plans, a provider was required to represent that the services billed were medically necessary. Medically necessary is defined by Medicare as “[h]ealth care services or supplies needed to prevent, diagnose, or treat an illness, injury, condition, disease, or its symptoms and that meet accepted standards of medicine.” What a holistic practitioner believes is appropriate treatment is not relevant to the definition of “medically necessary” unless it is also meets the “accepted standards of medicine.” The United States maintains that Dr. Shadoff is qualified to testify as to practices that meet “accepted standards of medicine.”

Defendant’s Reply reiterates his argument that Dr. Shadoff’s testimony is not relevant because Dr. Shadoff’s understanding of accepted standards of medicine differs from Defendant’s and Defendant and Dr. Shadoff employ distinct approaches and treatment protocols. By way of example, Defendant explains that in a typical case, if Defendant found a patient’s cholesterol level elevated, he would prescribe a statin instead of checking hormone or toxic metal levels. In

contrast, Defendant would never prescribe a statin but would search for the cause of elevated cholesterol by evaluating hormone and toxic metal levels and treat the patient with vitamins and chelation. Defendant contends this difference in treatment protocols illustrates that Dr. Shadoff's testimony, from the standpoint of a cardiologist, is improper.

The Court agrees with the United States that Dr. Shadoff's proffered testimony regarding the appropriateness of diagnoses and treatment provided by Defendant is undoubtedly relevant to the extent that such diagnoses and treatment were appropriate in the field of internal and cardiovascular medicine. *See Daubert*, 509 U.S. at 597 (proposed testimony must be "relevant to the task at hand"); Fed. R. Evid. 401. In reviewing Defendant's patient files and records, Dr. Shadoff opined:

The number of studies performed on each of these patients in a single work day would be physically impossible if done by reasonable technologists, even if assisted by Dr. Heilbron, suggesting that a number of these studies which were billed and reported were never actually done. This is in addition to the issue of not having the equipment available in the office to do a number of the procedures and studies. The repeated pattern of ordering medically unnecessary tests without appropriate documentation is reprehensible. These patients have been diagnosed by billing indication to insurers with serious cardiovascular problems that do not exist and would potentially result in unnecessary testing and management by either Dr. Heilbron or other medical providers in the future.

Doc. 37, at 7. Based on his experience, knowledge, and training, Dr. Shadoff concluded for example that more than 63 patient exam reports were identical, which led him to the conclusion that each report was a copy and that Defendant had a standard report that was simply inserted into patient charts and that he did not actually perform complete examinations. *See* Doc. 37, at 2. Moreover, Dr. Shadoff determined that more than 80 Echocardiogram reports were on a standard form and appeared to be the same copies because they showed the exact same results. *See id.* Dr. Shadoff opined that it is biologically inconceivable that so many patients would have the exact same Echocardiogram results. *See id.* Dr. Shadoff also reached specific opinions

regarding the nine patients' medical charts. For example, Patient C had "no documented cardiovascular or respiratory complaints and a normal documented physical exam." *Id.* at 4. Yet, Defendant ordered studies and allegedly performed them in his office when there was "no medical indication for any of the studies" and "no medical documentation that reflects the billing indication and diagnoses" for tests ordered. *See id.* at 4–5. Such testimony undoubtedly helps the trier of fact determine the facts at issue in this case, such as whether Defendant fraudulently ordered and performed medically unnecessary tests, submitted false claims, and misused coding modifiers. *See Jordan*, 485 F.3d at 1218 ("[A] fact is 'of consequence' when its existence would provide the fact-finder with a basis for making some inference, or chain of inferences, about an issue that is necessary to a verdict," but it only need to have "any tendency" to do so).


The Court finds Dr. Shadoff's testimony is relevant because Defendant diagnosed patients with certain cardiovascular problems. Dr. Shadoff is a cardiologist, and the Court has already determined he is qualified as an expert in cardiology and his testimony is reliable. The Court is not convinced by Defendant's argument that Dr. Shadoff's testimony is not relevant because Dr. Shadoff is not an expert in holistic medicine. As the United States points out, none of the healthcare insurers credentialed Defendant as a practitioner of holistic medicine. The insurers evaluated Defendant's patient diagnoses based on what was medically accepted for cardiovascular and internal medicine. Defendant did not submit claims for holistic services, and in fact, the healthcare insurers did not even pay claims for holistic services. Stated simply, Dr. Shadoff's testimony is relevant because it bears upon issues at the heart of this case including whether Defendant knowingly falsified patient records, submitted false claims to insurers, and ordered medically unnecessary tests. *See Daubert*, 509 U.S. at 591. The Court therefore agrees with the United States that Dr. Shadoff's proffered testimony is relevant to whether the services

for which Defendant submitted claims were medically necessary.

In sum, the Court finds and concludes that Dr. Shadoff's testimony as a physician specializing in cardiology and internal medicine meets the requirements under *Daubert*. Dr. Shadoff's knowledge, skill, experience, training and education satisfy *Daubert*'s qualification requirements. Also, in considering the facts of this particular case, the Court finds Dr. Shadoff's testimony to be reliable under the standard set out in *Daubert*. Finally, the Court finds Dr. Shadoff's testimony will helpful in assisting the jury in deciding the ultimate factual and legal issues in this case.

THEREFORE,

IT IS ORDERED Defendant's Motion (**Doc. 30**) is hereby **DENIED** for the reasons described in this Memorandum Opinion and Order.



UNITED STATES DISTRICT JUDGE